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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,953	01/29/2004	Amedeo Leonardi	20199/100M275-US1	4561
7278	7590	01/12/2006		
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			EXAMINER LEWIS, AMY A	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/768,953

Applicant(s)

LEONARDI ET AL.

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-49, drawn to a method of treating neuromuscular dysfunction of the lower urinary tract comprising administering a compound having selective affinity for the mGlu5 subtype of the metabotropic glutamate receptors, classified in class 514, subclass 277.
- II. Claims 50-58, drawn to a method of identifying a compound useful for treating neuromuscular dysfunction of the lower urinary tract comprising identifying binding affinities for an mGlu5 receptor, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I and II are directed to patentably distinct inventions. These methods are distinct since the practice of the invention of Group I does not require the particulars of the screening assay of Group II nor does the assay of Group II require the practice *per se* of the method of treatment of Group I. For example, one would not need to identify the binding affinity of a compound for mGlu5 receptors in order to administer the compound in a method of treatment. Nor would one necessarily need to administer the compound in a method of treatment after screening a compound for its binding affinity for mGlu5 receptors; the compound could simply be screened for affinity to the mGlu5 receptor.

*Election of Species*

Applicant is required under 35 U.S.C. 121 to elect one of Inventions I or II and in addition, a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The species of compounds with selective affinity for the mGlu5 receptor are as follows:

- a. Compounds of Formula I
- b. Compounds of Formula IA
- c. Compounds of Formula IIA
- d. Compounds of Formula IIB
- e. Compounds of Formula III
- f. Compounds of Formula IV
- g. Compounds of Formula VA
- h. Compounds of Formula VB

Should Applicant elect the invention of Group I, Applicant should also elect *one specific compound* for the practice of the invention, which falls within the criteria of *one of* Formulas I through VB wherein *every* variable is identified. For example, the compound 2-methyl-6-(phenylehtynyl)pyridine (MPEP), which meets the criteria of Formula I.

The species election will be given effect in the event that the Markush-type claims are not found allowable at which time the examination of the claims presented will be limited to the

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Markush-type claims and claims directed solely to the election made as to items a-h. The claims directed to nonelected items will be held withdrawn from further consideration. The election is a requirement for restriction. *In re Herrick*, 1858 CD 1, and *In re Joyce*, 19558 CD 2.

Applicant's response must include a provisional election of a single species wherein all variables are specifically defined and must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a claim generic with regard to item C above, applicant will be entitled to consideration of claims to additional species of item C above which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis  
Patent Examiner  
Art Unit 1614

A handwritten signature in cursive script, appearing to read "Amy Lewis".

Christopher Low  
SPE  
Art Unit 1614